

Northwestern BCIC CTIM Standards in Context Module

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INSTRUCTOR VERSION WITH NOTES

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Teaching with this module can take between two and three 90-minute class sessions (depending on nature and extent of discussion) in addition to the included negotiation exercise. Depending on course context and level of students, slides may be modified or omitted. The module is intended to fit into a range of courses but has a slant toward innovation and management. It also is presented from a corporate perspective more than a policy or societal one. Healthcare and smart grid are used as examples. Reading are suggested (standards specific and some broader) with summaries, links to internet sources and some discussion guidance.

SUGGESTED READINGS (fitting slides)

READ:

Standards for business - How companies benefit from participation in international standards setting (de Vries)
<http://www.iec.ch/about/globalreach/academia/pdf/vries-1.pdf>

Developing global health technology standards: what can other industries teach us? (Masum, Lackman and Bartleson)
<http://www.globalizationandhealth.com/content/9/1/49>

SKIM

Why Innovation In Health Care Is So Hard (Herzlinger)

<http://hbr.org/web/extras/insight-center/health-care/why-innovation-in-health-care-is-so-hard>

International Standards: The Challenges for an Interoperable Smart Grid

White paper from Schneider Electric USA. Available at: <http://www.slideshare.net/SchneiderElectric/international-standards-2012-17230139>

Why Standardization Efforts Fail (Cargill)

<http://quod.lib.umich.edu/j/jep/3336451.0014.103/--why-standardization-efforts-fail?rgn=main;view=fulltext>

Evolving Roles of Standards in Technological Innovation - Evidence from
Photovoltaic Technology (Ho and O'Sullivan)

http://druid8.sit.aau.dk/acc_papers/dftxtpfir8g7gcyrs1j66arx9sin.pdf

Discuss the following. Why might this be so and what are implications?

"Third-class companies make products; second-class companies develop technology; first-class companies set standards."

-- Modern Chinese Proverb

quoted in Bach, David, Abraham L Newman, and Steven Weber. (2006). "The International Implications of China's Fledgling Regulatory State: From Product Maker to Rule Maker." *New Political Economy* XI, (4, December), p.504.)

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Importance of standards and participation in standards development (as will explore further)

Reflecting growing international challenge to US firms, China is increasingly successful in international standards setting in part by raising questions and challenges requiring proliferation of committees that only China has personnel resources to join, but also through increased sophistication in negotiation.

SMART GRID AND THE ROLE OF STANDARDS

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Although if or how this section is included may vary based on course settings, the intent is to begin with context and then move more into standards to help students overcome lack of awareness/interest in standards and/or preconceptions of how standards impact. Energy concerns (an instructor might even begin earlier encouraging the class to brainstorm why climate change is such a difficult problem with multiple interplaying parts to the problem and solution) and smart grid is well known as an emerging area. NIST is also playing a strong coordinating role in smart grid offering further material and potential for guest speakers if desired. The interplay with *smart manufacturing* (advanced manufacturing) could also be explored. Later readings and slides add healthcare as an additional such high profile example.

WHAT IS THE SMART GRID?

According to US Department of Energy (DOE):

- Smart Grid is the term used for an electricity delivery system that is integrated with modern digital and information technology to provide improved reliability, security, efficiency and ultimately lower cost to the user.

DRIVING PROBLEMS

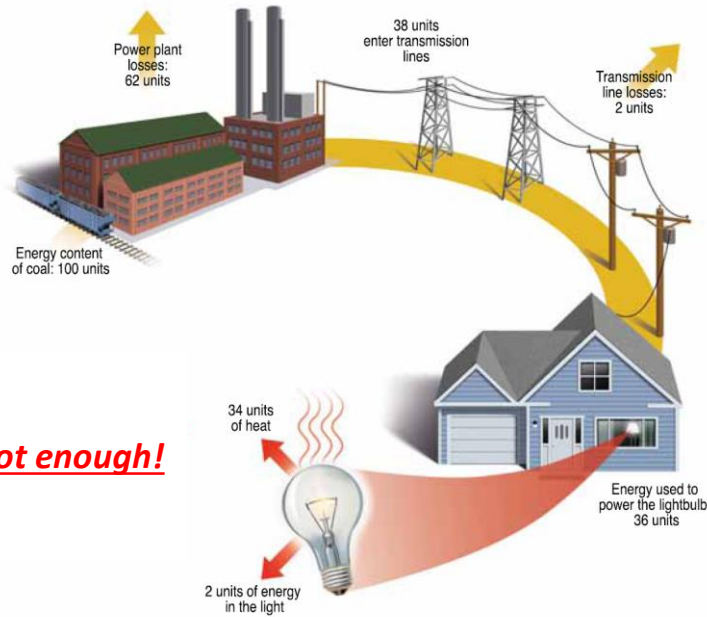
Reliability – current system is overburdened resulting in increasingly common and costly shutdowns/ brownouts

Efficiency – only 30% or less of energy consumed is actually used by the customer

Affordability – energy costs are rising

Environmental impact – 60% of world energy is from burning coal; renewable energy sources are difficult to integrate into existing grid

But more broadly the energy industry is dealing with accelerating geopolitical competition, accelerating pace of change in core technologies, accelerating regulatory change, increase in usage and changes in customer demographics impacting usage patterns



Supply is not enough!

Source – “what you need to know about energy” – us nat acads⁶

THE VISION OF THE SMART GRID

Smart Grid Characteristics

MODERN GRID
STRATEGY

The Smart Grid will:

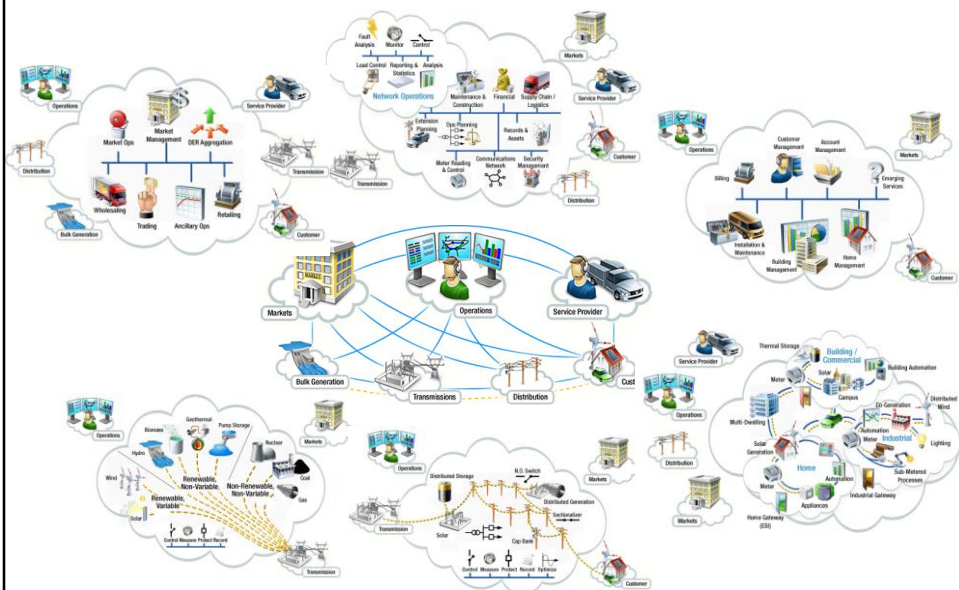
- Enable active participation by consumers
- Accommodate all generation and storage options
- Enable new products, services and markets
- Provide power quality for the digital economy
- Optimize asset utilization and operate efficiently
- Anticipate & respond to system disturbances (self-heal)
- Operate resiliently against attack and natural disaster

DOE SmartGrid Implementation Workshop – June 2008 – Vision and Metrics



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SMART GRID DOMAINS – complex with many stakeholders



<http://smartgrid.ieee.org/ieee-smart-grid/smart-grid-conceptual-model>

What are barriers to smart grid implementation? (examples)

- Cost (estimates are grid transformation could cost well over a trillion dollars)
- Storage systems particularly for renewable energy are not well developed
- There are multiple uncertain development paths with changing technologies, changing energy mix, changing policies
- Utility cultures and policies as well as regulatory framework will need to change including decoupling to ensure utilities earn an equivalent return pushing investment in efficiency, support for distributed energy resources (DER) allowing businesses and residences to generate power to supplement grid use and even sell back (relationships with consumers will need to change as some become producers)

- Consumer billing will change allowing more consumer info and control – and requiring complex decisions
- Even as overall system costs come down, pay by individual consumers and businesses may go up; manufacturers fear being pushed to unprofitably shift power usage (even shut down systems, costly to restart)
- Other fears: RF radiation as all devices using power become smart and continually transmit information with uncertain long term impact on humans and other species; loss of control as utilities can remotely adjust usage; Machiavellian polices to encourage efficient power usage (IBM Singapore smart traffic lights)

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The IBM Singapore reference is to a system now in place that changes traffic signal frequency on different roads to encourage driving on specific routes at specific times.

STANDARDS AND SMART GRID

Standards will be critical related to Smart Grid offering:

- essential common data formats, controls and performance measures across devices, systems, sensors and organizations (including multiple vendors)
- potential consensus selection of development paths
- vehicles for companies to balance individual strategic and operational requirements with implied cross organization/cross-sector, even cross-national environmental and efficiency initiatives
- support for innovation by giving confidence that new products, technologies and processes will be compatible with legacy systems, infrastructure and vendor capabilities, and will be accepted in the market
- support for development of reporting requirements recognizing varying levels of understanding, contexts and proprietary concerns

NIST SMART GRID STANDARDS DEVELOPMENT CRITERIA (excerpts)

- Enables the transition of the legacy power grid to the Smart Grid.
- Has, or is expected to have, significant implementations, adoption, and use.
- Is supported by an SDO or standards- or specification-setting organization (SSO) such as a users group to ensure that it is regularly revised and improved to meet changing requirements and that there is a strategy for continued relevance.
- Is developed and adopted internationally, wherever practical.
- Is integrated and harmonized, or there is a plan to integrate and harmonize it with complementing standards across the utility enterprise through the use of an industry architecture that documents key points of interoperability and interfaces.
- Addresses, or is likely to address, anticipated Smart Grid requirements identified through the NIST workshops and other stakeholder engagement.
- Allows for additional functionality and innovation

See *NIST Framework and Roadmap for Smart Grid Interoperability Standards, Release 2.0* Office of the National Coordinator for Smart Grid Interoperability Engineering Laboratory in collaboration with Physical Measurement Laboratory and Information Technology Laboratory, February 2012, pp 64-65 Available at: www.nist.gov/smartgrid/upload/NIST_Framework_Release_2-0_corr.pdf

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Illustrates increasingly important features and trends in standards development. Note consistent with “quality” standard discussed later. It is worth stressing that standards development needs to consider range of stakeholders – recall the complexity of stakeholders in smart grid.

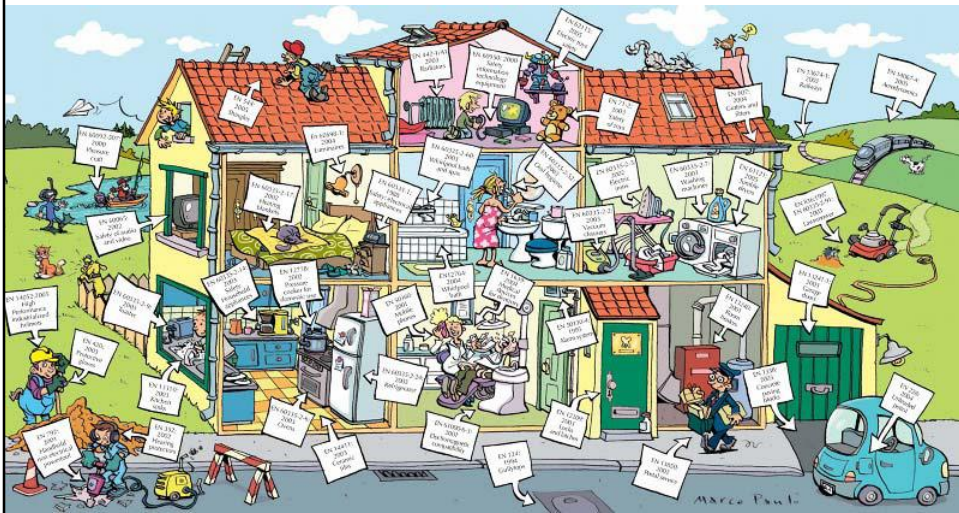
ANOTHER QUICK EXAMPLE: CLOUD COMPUTING

As intended, can provide ubiquitous virtual on-demand internet/network-based access to storage, servers, software and applications – reducing capital expenditure and need for in-house expertise, while increasing flexibility in media, work location and collaboration.

But **well designed standards** are needed to address issues and concerns for:

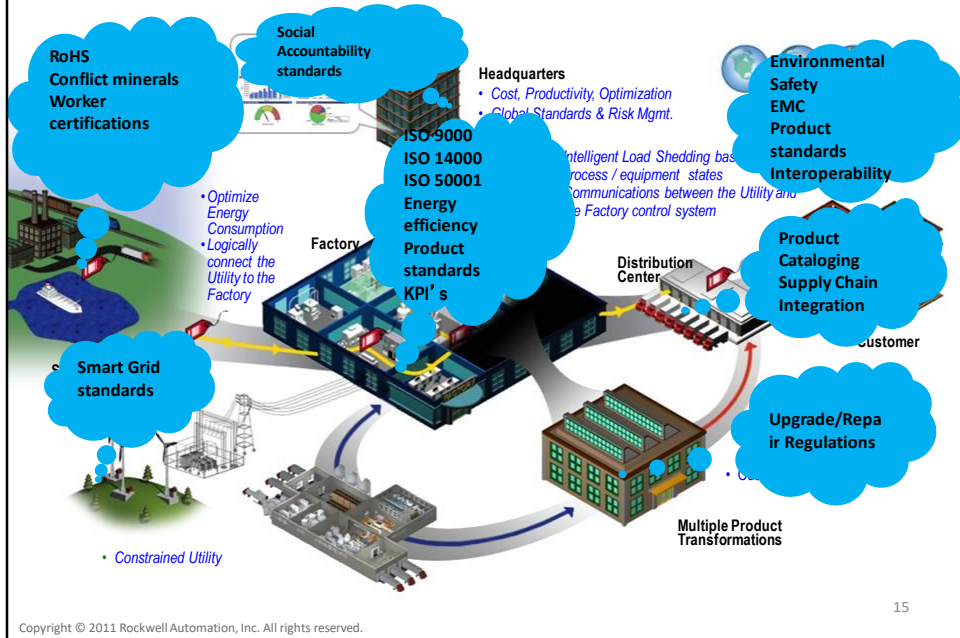
- Migration paths
- Service choices
- Security
- Needed interoperability and portability across global infrastructure, devices and regulatory frameworks

STANDARDS



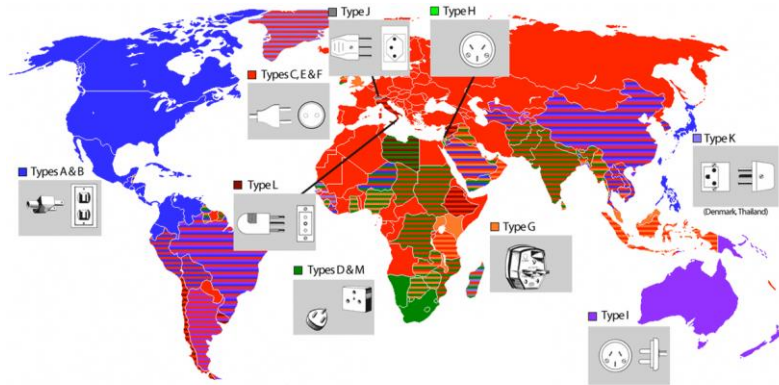
From Prof. dr. Knut Blind, Standardization: A Catalyst for Innovation ERIM, 2009

Standards in all aspects of the supply chain...



(animated)

STANDARDS TOO LATE



Type A&B
US Plug

Type C E&F
EU Plug

Type G
UK Plug

Type D&M
ZA&IN Plug

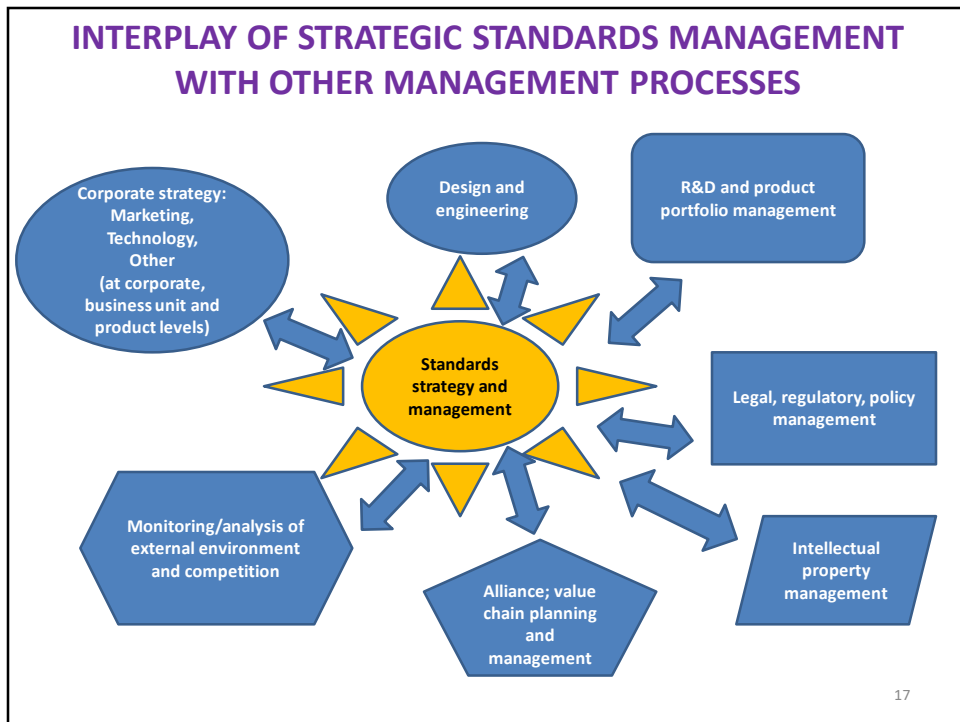
Type H
Israel Plug

Type I
AU Plug

Type J
CH Plug

Type K
DK Plug

Type L
IT Plug



It could be mentioned here that within corporations, it is common for corporations to make one of two errors in positioning standards management in the planning process; either standards management is considered to be simply a (relatively trivial) aspect of broader planning requiring little specific attention – or standards are considered to be a unique challenge isolated from other planning activity requiring wholly new models and approaches. Standards management should be interconnected with other functions taking account of their needs and issues and, in turn, informing them; and should adapt relevant models and processes. Thus, as one example, the negotiation exercise later in the module adapts general negotiation theory while recognizing unusual requirements in standards negotiation. The exercise also brings out broad strategic concerns that may be impacted by the evolving standard.

WHAT IS A STANDARD?

Definitions vary and the term is used for a wide range of things ranging from academic standards to codes of conduct to “standards of excellence”. Standardization can refer to developing a standard or designing a product for use in multiple markets. We will consider technical standards. Unlike *regulations* which are mandatory, standards use is considered voluntary.

Moving from simple to complex:

A standard is a document that establishes uniform engineering or technical specifications, criteria, methods, processes, or practices.

Wikipedia, 2009

An agreed upon response to a recurring problem – perceived, anticipated, or real – that is codified for the purpose of communication.

Moen, 1998

De Vries (1997) defines standardization as: *an activity of establishing and recording a limited set of solutions to actual or potential matching problems directed at benefits for the party or parties involved balancing their needs and intending and expecting that these solutions will be repeated or continuously used during a certain period by a substantial number of the parties for whom they are meant.*

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Note – on an international level the WTO tries to “enforce” standards compliance to a degree. Regulations may reference standards.

DEFINITION OF STANDARDS (CONTINUED)

The important International Organization for Standardization (ISO) adds a couple dimensions indicating Standards are documents achieved ***by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results aimed at the achievement of the optimum degree of order in a given context.***

OUR DEFINITION:

A technical Standard is a documented and industry/market applied agreement containing uniform engineering or technical guidelines to ensure that materials, products, processes, practices and/or services can be consistently produced and used and remain adequate for their purpose within a given context. This includes ensuring safety and enabling required interoperability with other materials, products, etc.

STANDARDS IS CALLED THE “LANGUAGE OF INFRASTRUCTURE” – WHY?

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Could discuss ISO' s perspective, noting the inclusion in the definition of “consensus”, “approved by recognized body” and “optimum degree of order”.

A “QUALITY” STANDARD

- clear, not vague or with internal contradictions; as simple as possible
- As relevant, backward (legacy) compatible and/or support transition
- potential to be platform for innovation; allows flexibility
- consensus developed and addresses stakeholder concerns
- likely to be implemented in market and by industry
- timing appropriate to support market growth and investment.

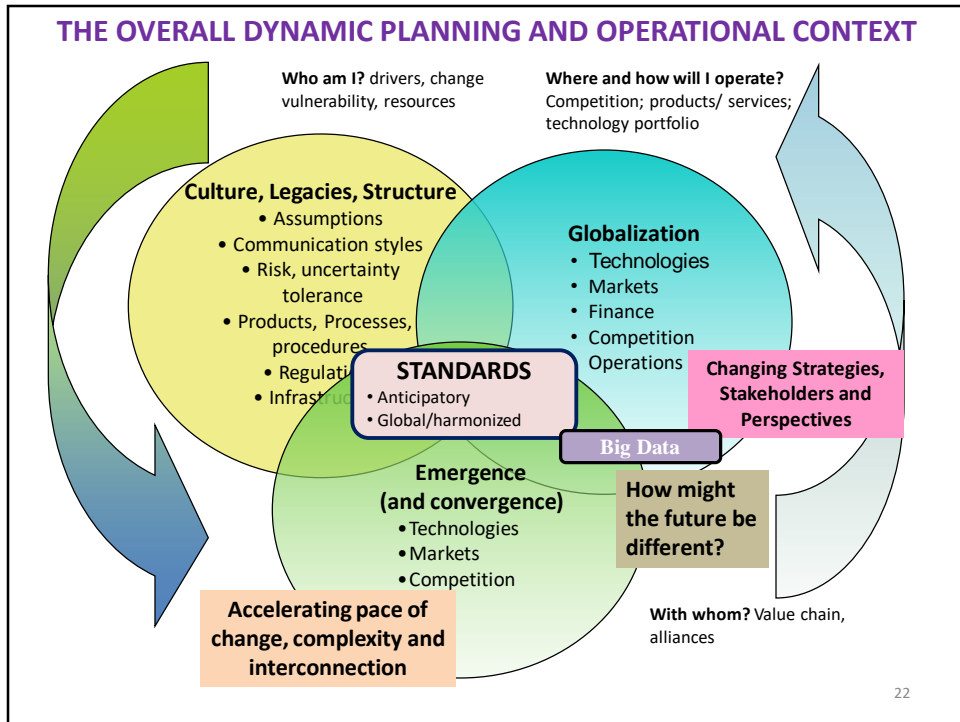
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There is often a tradeoff between achieving consensus, addressing concerns and timing of standards introduction. The need for standards to be accepted and implemented can be overlooked.

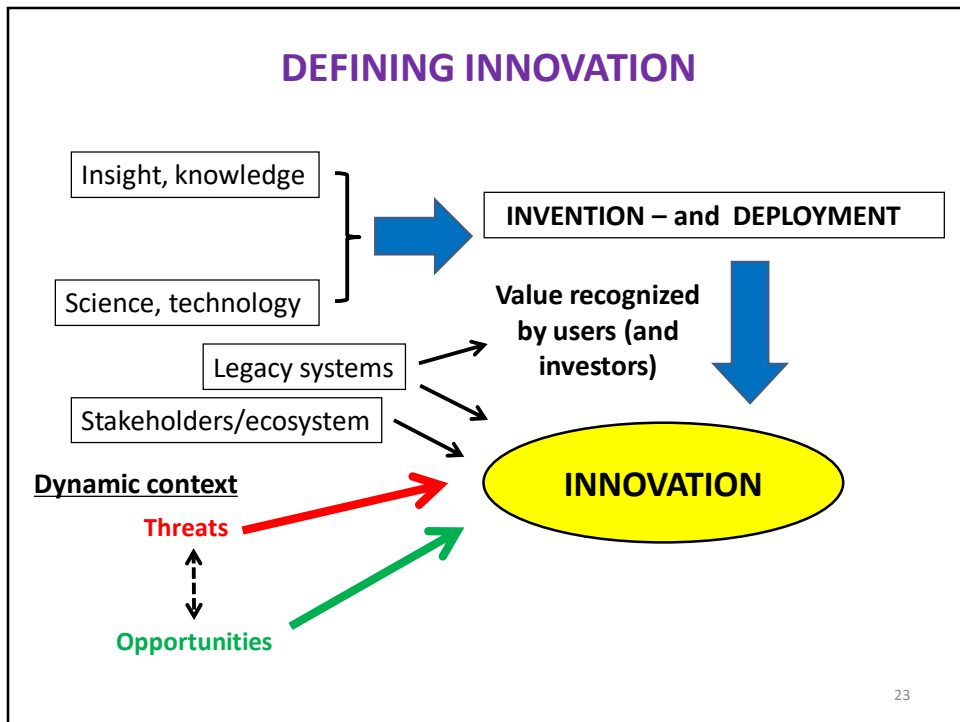
WHY ARE STANDARDS SO IMPORTANT?

- Safety
- Interoperability; may also support modularity
- Facilitate transition from legacy to emerging systems
- Efficiency, flexibility, reduce cost (multiple suppliers)
- Reduce (technical) risk
- Level technical playing field
- Capture and support knowledge transfer
- Support/ stimulate innovation – **we will discuss this a bit further**

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As prelude to further considering the impact of standards with a focus on innovation, let's look at how standards interplay with interrelated change factor in the dynamic overall planning and operational context (slide is animated) with some key management questions. Emergence (new technologies and fields – increasingly science rather than engineering based) and convergence (once distinct fields increasingly overlapping) is a particular challenge to ensuring proper representation and knowledge base in standards development



Innovation is not the same as invention. Rather it is a new approach that has market value. Innovation success generally requires reconciling with legacy systems and approaches, user needs and competitive technologies or products (which can be opportunities or threats or even both in varying ways for a new approach) and also assessing and managing stakeholders and assembling the needed support ecosystems. These are not static but dynamic as conditions change. Innovation also requires support from investors who must see value that exceeds perceived costs and risks.

STANDARDS AND INNOVATION

**Do standards inhibit or stimulate innovation
- or both? How and what determines the
impact?**

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Discussion – next slide lists factors on both sides

EXAMPLE CONSIDERATIONS

INHIBIT	STIMULATE
Lock-in solutions blocking potentially better approaches	Enable platforms; support subsequent generations of innovation; allow focus on component level innovation
May particularly delay or inhibit radical innovation	Ensure innovations will work with legacy infrastructure and systems (may support transition)
May reduce choice and competition across approaches	May stimulate competition (within standard defined domain); push incremental innovation
In a new field, knowledge required to inform standards may be limited	Reduce cost of change and facilitate trade of complex products
Participation in standards development may be difficult for smaller firms including entrepreneurs	Give investors, consumers and innovators confidence, may grow market including government procurement
	May enable global, cross-sector and cross-system collaboration

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Impact likely depends on wording of standard, whether the standard specifies design versus performance, who is involved, and perhaps most importantly: timing (as next slides consider)

EVOLVING CHANGES IN STANDARDS (AND STANDARDS DEVELOPMENT)

Drivers:

- globalization
- increased complexity, uncertainty and pace and extent of change

Two examples of standards evolution:

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(animated)

1. Reactive (responsive) to *anticipatory* (proactive) to provide platforms/foundation for corporate planning/ technology selection and decisions and innovation

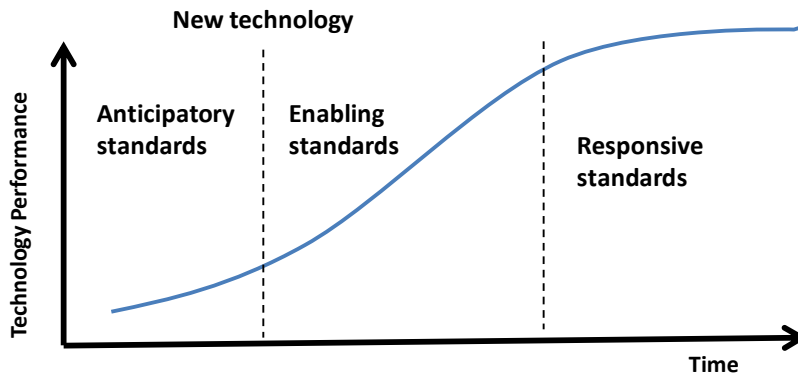
Challenges?

- Standards process has traditionally been slow and deliberate – now need to be more rapid
- How support transition from legacy systems and prior standards?
- How maintain flexibility and support innovation, avoiding choosing an approach too soon? How define scope of standard?
- What does the anticipatory standard build on, what is relevant?
- Who should /must participate in anticipatory standard development? (may inherently cross traditional boundaries)
- How deal with the wider than usual variation in understanding and knowledge among developers?
- Other?

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Discuss challenges – then click to list issues

STANDARDS AND TECHNOLOGY LIFECYCLE – THE TIMING ISSUE



Derived from Sherif, A Framework for Standardization in Telecommunications and Information Technology, IEEE Com. Mag. 2001

Considerations at different phases:

- varying stakeholders, players, agenda, and roles
- identification and integration with existing/legacy technologies, processes and standards
- supporting versus constraining innovation
- determination of best standards development process
- different degrees of standardization are optimal at different points in the technology's evolution

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Anticipatory standards specify the production system of the new technology. For instance, they define any new concepts and components needed to proceed with trial implementations and are critical for widespread acceptance of a product or service. Participatory {or enabling} standards are generated when the knowledge of the technology is diffused and products start to be commercialized. Note that in general US standard setting still tends to be reactive whereas China seems to have a clearer standardization strategy with an emphasis on anticipatory standards.

Different degrees of standardization are optimal at different points in the technology's evolution.' Managing the timing of standards therefore poses strategic issues. Enabling standards are intended to control without overly constraining market evolution. Responsive standards may be designed to help ensure compliance.

Should also note here the difference between "defacto" (market determined, effectively no standards setting process, reflects dominant market position) standards and "dejure" – formal standards (developed through a formal process by Standards Development Organizations (SDOs) – or by consortia as will be discussed later.)

2. Country-specific to harmonized

Challenges?

- danger of setting to lowest common denominator
- may gloss over important local variations
- accentuates political issues and cross-cultural/national factors in negotiation

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Discuss challenges then click to show some issues.

OTHER TRENDS

Increased incorporation of *Standard Essential Patents*

Design/ prescriptive  performance

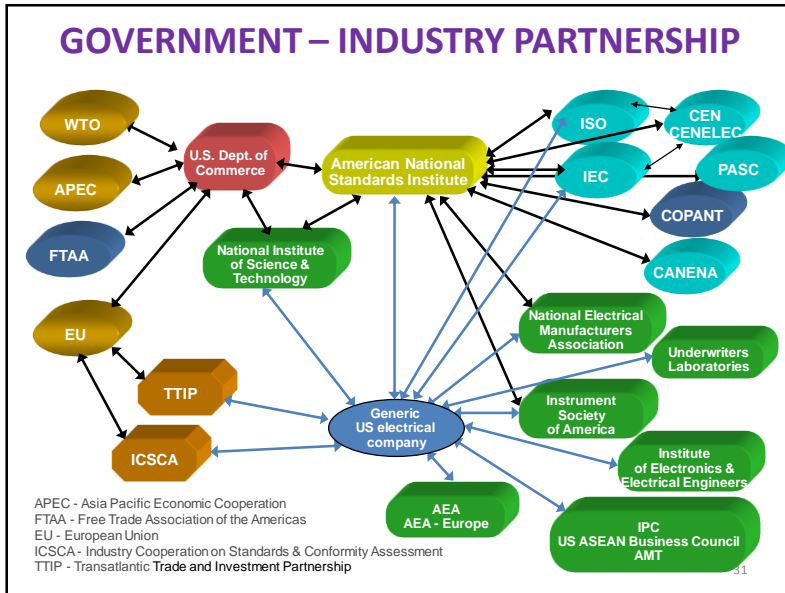
Governments; SDO's  industry consortia

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Companies pushing to have standards favor their approaches and gain advantage are succeeding in getting their patents incorporated. They are required to offer “Fair, Reasonable and Non-Discriminatory” (FRAND) licenses, but, particularly when multiple such patents may be incorporated, standards can become costly (and FRAND can be subject to challenge.)

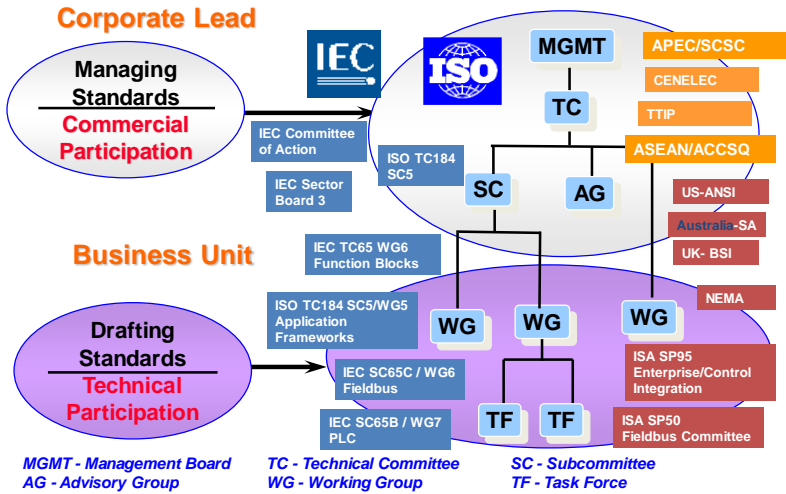
Design – performance is question of degree and nature of specificity. Design tells precisely how something should be done whereas performance specifies goal and interoperability requirements but leaves approach up to manufacturer/innovator. Trend is because it has become much harder to keep track of technology changes and potential and also it is more critical to stimulate and enable innovation. BUT it can be harder to designate measures/tests (steps toward compliance) for performance standards and to appropriately set targets.

Trend to consortia will be discussed as we review who develops standards and how (note Gov; SDO's (Standard Development Organizations) – “traditional”)



This and the following slide illustrate the multitude of standards developing entities with which a US electrical company (as an example) might choose to engage (and how.)

HOW MIGHT A US ELECTRICAL COMPANY PARTICIPATE IN STANDARDIZATION?



WHO DEVELOPS STANDARDS AND HOW

Formal/"de jure" (as opposed to de facto dominant market position determined) standards are developed by:

INTERNATIONAL:

- non-governmental organizations (NGOs) organizations with countries as members such as
 - International Electrotechnical Commission (**IEC**);
 - International Telecommunications Union (**ITU** – actually part of the UN), and
 - International Organization for Standardization (**ISO**.) (Note the US based Institute of Electrical and Electronics Engineers (**IEEE**), for example, also has global but primarily individual private sector members.) There are also regional bodies such as for Latin America, Europe, Africa, Caribbean, and Asia-Pacific among others.
- Enforcement of international standards comes officially through the World Trade Organization and the associated Technical Barriers to Trade (TBT) agreement and an arbitration system punishing non-compliance. This is actually rarely used.

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This is a simplified summary.

ISO is the world's largest developer of voluntary international standards with nearly 20,000 standards covering almost all aspects of technology and business from food safety to computers, and agriculture to healthcare as well as process standards such as ISO 9000 quality control

ISO has 160 member countries.

WHO DEVELOPS STANDARDS AND HOW (2)

As is true of most national level formal standards organizations, work is done through **technical committees** formed around technology foci (within ISO there are over 3000 committees) and in turn, often through **working groups**. Whereas each country has a single vote, companies and others may participate on behalf of their country on committees/groups.

WHO DEVELOPS STANDARDS AND HOW (3)

NATIONAL LEVEL FORMAL STANDARDS SETTING

In most countries a central entity, usually part of the government, has primary responsibility for standards development. In the US, the American National Standards Institute (**ANSI**) helps coordinate the essentially private sector voluntary US standardization system, certifies “national standards” and represents the US in ISO, and the National Institute for Standards and Technology (**NIST**) coordinates government standards usage and collaboration with industry (and carries out research underpinning standards). **But neither develops standards.**

WHO DEVELOPS STANDARDS AND HOW (4)

Instead this is done on the formal level by largely sector oriented **Standards Development Organizations** (SDOs) composed of individual professionals and industry associations. Examples include IEEE, ASTM International, American Society of Mechanical Engineering (ASME), Society of Automotive Engineers (SAE) and the National Electrical Manufacturers Association (NEMA.)

For standards certified by ANSI as national standards, all appeals (objections) by anyone “materially impacted” must be addressed at any time – a process that can take years. Such standards must also be reviewed at least every 5 years.

WHO DEVELOPS STANDARDS AND HOW (5)

INFORMAL STANDARDS SETTING: CONSORTIA

Beginning especially with the information and communication sectors characterized by rapid development and short product shelf lives (windows of opportunity), “like-minded” groups of companies and other parties focused on specific market problems have formed consortia to address gaps in standards.

But consortia have become increasingly common and perhaps preferred as a means of developing standards.

WHO DEVELOPS STANDARDS AND HOW (5)

Prominent example: **World Wide Web Consortium (W3C)** –

- Founded in 1994 by MIT with support from the EC and DARPA (US Dept. of Defense) now jointly hosted by MIT, the European Research Consortium for Informatics and Mathematics (ERCIM – in France), Keio University (Japan) and Beihang University (China) with offices in 17 other world regions
- Goal: lead the World Wide Web to its full potential by developing {common} protocols and guidelines that ensure the long-term growth of the Web
- Application for membership must be reviewed and approved by W3C with a sliding scale, depending on the character of the organization applying and the country in which it is located

Why and how are consortia different from “traditional” SDOs?

SDO's versus Consortia

Ongoing debate over comparative efficacy and even legitimacy - less so recently with greater collaboration between the two, and increased use of communication technology and media in SDOs. To a degree SDO committees work like consortia.

SDOs versus Consortia in emphasis

SDOs	CONSORTIA
Process oriented	Market-driven
Consensus to build common interests; participation from all stakeholders	Speed; like-minded, maybe stress on commercial interest (but as in W3C includes others)
Technical focus	Strategic focus
Small budget from sponsorship, gov. grants, document sales; low membership fees	Significant budget from high (maybe sliding) membership fees - "pay-to play"
Avoid IPR conflicts; voluntary FRAND	Embrace IPR – negotiate licensing
	More likely to include active support for conformance testing and promotion of standard in market (but SDOs also derive revenue from testing)

Derived from: Schoeche, T. (2009). *Standardization and Digital Enclosure*. Information Science Reference, 2009

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SDOs are criticized as too slow to address dynamic market needs; Consortia criticism: omits key stakeholders fro inclusion and even for effective standards and in highly complex systems, critical players may not be evident at outset. **Either** may be dominated by one or a small group of organizations. Concern for consortia: groupthink.

The Schoeche document (source for chart content) is also available at:

[http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCkQFjAA&url=http%3A%2F%2Fhumanities.cn%2FRecommended%2FLinux%2FStandardization and Digital Enclosure The Privatization of Standards Knowledge and Policy in the Age of Global Information Technology Advances in .pdf&ei=Sfy6UsegH8LcyQGw2YCIDQ&usg=AFQjCNEfBPPp-VcOWui -suCNITof_sGng&bvm=bv.58187178,d.aWc&cad=rja](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCkQFjAA&url=http%3A%2F%2Fhumanities.cn%2FRecommended%2FLinux%2FStandardization%20and%20Digital%20Enclosure%20The%20Privatization%20of%20Standards%20Knowledge%20and%20Policy%20in%20the%20Age%20of%20Global%20Information%20Technology%20Advances%20in%20.pdf&ei=Sfy6UsegH8LcyQGw2YCIDQ&usg=AFQjCNEfBPPp-VcOWui-suCNITof_sGng&bvm=bv.58187178,d.aWc&cad=rja)

READINGS DISCUSSION

- deVries (International Standardization as a Strategic Tool)
- Cargill (Why Standardization Efforts Fail)
- Healthcare
 - Herzlinger (Innovation reading)
 - Masum, Lackman and Bartleson (Developing global healthcare technology standards)
- Ho and O'Sullivan (Evolving Roles of Standards – PV)

deVries (International Standardization as a Strategic Tool)

Summary

Provides specific cost-benefit examples including:

Tyco – successfully pushed European and International standards that referenced their technology. Resulting advantage: compared to competitors, time to market (early mover) and related economy of scale, depth of understanding of standard foundation. The international standard effectively superseded American standard which was primarily based on competitor (Lucent.)

Intergraph – through participation in standards development, learned of change in requirement saving money.

Wassenberg Medical Devices - small company successfully pushed top quality standard at level competition could not readily meet. This became basis for British gov procurement with a disease outbreak.

Unnamed electrical equipment maker – altered testing requirement for a standard reducing potential damage to components.

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Why Standardization Efforts Fail (Cargill)

Selected types of "failures"

- **Fail to achieve consensus.** But in example of Sun twice withdrawing standard proposal, Cargill notes benefit to Sun in gaining development time, blocking competitors who delayed effort pending a possible standard, and ultimately achieving a defacto standard
- **"Feature creep"** need to split standard into smaller focused specification
- **Market ignores** often due to failure to address needs and/or addressing technologies that have already been superseded
- **Implementations incompatible** – similar to above but effectively, developers ignore standard. May be due to poor specification or understanding
- **Standard used to manage market** – may reflect "essential patents" incorporated in standard carrying excess royalty or other costs for implementation

Comments?

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Raises important points. The split standard partial solution to feature creep could be emphasized as this may come up in the negotiation exercise.

Why Innovation in Health Care is So Hard (Herzlinger)

What factors does Herzlinger indicate or imply as barriers – and how can they be addressed?

What are different categories/types of health care innovations?

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- health care fragmentation
- problems are highly complex and interrelated
- multiple and powerful stakeholders with competing agenda
- funding and investors expectations (and poor understanding); complex cost factors
- interplay of technology and delivery/infrastructure
- interplay of prevention, education, diagnostic, treatment
- but also culture laden

Types of innovation

- structural (non-traditional locations e.g., home, retail; growing specialization)
- technology (diagnostic, treatment incl, customized drugs, IT connections, digital health)
- financial
- regulatory

**Healthcare Stakeholders (US) that should be represented –
how many can you name?**

- Physicians (general and specialists)
- Patients and families, caregivers
- Pharmacies
- Insurance companies
- Managed Care companies (HMO' s, PPO' s)
- Drug companies
- Hospitals; long-term care facilities (public and private)
- Clinics, including retail clinics
- Government regulators
- Government funding (Medicare, Medicaid, VA)
- Laboratories
- Medical device developers (from a growing number of sectors)
- Technology developers' and investors
- Medical schools and training programs
- Society; others?

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In principle, all stakeholders should have a voice in standards setting. This list is brainstormed (not from any individual reading) and again reflects complexity.

Developing global health standards

Notes some challenges in healthcare (others indicated by Herzlinger) including

- fragmentation and diversity in device industry along multiple dimensions with many entities creating technology.
- Industry cannot afford any errors.
- Development is research intensive –could benefit from modularization.
- Accurate data flow through system important.
- Especially in developing countries – low resources, must be sure of investment and, ideally, need price reduction through choice of vendors and ability change vendors.

Incentives for standards:

- Recognize value of interoperability
- Reduce cost of innovation; enhance potential small developers license to large or jointly develop
- Enable adapt tech to local needs, integrate with local innovation

Summarizes experience in other industries considering economic and tech viewpoints; relevance to healthcare

Thoughts? Lessons transferable? How could standards address Herzlinger obstacles?

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Evolving Roles of Standards – PV (Ho and O’Sullivan)

Authors illustrate the interplay of innovation and standards with the case example of the evolution of photovoltaic technology as a viable alternative energy. They note the early role of standards in enabling consolidated government and legislative support and later in encouraging PV commercialization (moving from technology development to application) and user acceptance through the establishment of quality and safety standards.

Also note problems due to delay in standards including lack of interface standards hindering production ramp up and lack of broader manufacturing standards increasing variability in processes preventing needed data collection for process control and improvement.

Authors also discuss technology lifecycles and standards which we will consider later.

QUALCOMM IN CHINA

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The Qualcomm case illustrates the fact that factors beyond the technical merits of a standard have major impact (politics – domestic and international, relationships, national development priorities, etc.)

CONSIDER THESE NEWS BULLETS – WHAT IS UNDERLYING THEM? WHAT MIGHT THEY IMPLY? WHAT DON'T YOU KNOW?

ON

- March 1993: Qualcomm conducts first meetings about CDMA with Chinese officials.
- December 1993: Qualcomm signs agreement in Beijing to conduct CDMA field trials.
- April 1994: Qualcomm begins testing CDMA in China.
- October 1994: Qualcomm calls field tests a "complete success."

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STILL ON

- November 1996: China's Great Wall Mobile Communications (gov' t created entity to deploy CDMA) drafts plan to build CDMA network.
- May 1997: Qualcomm signs deal to sell wireless phones to Great Wall.
- July 1997: The Asian economic crisis begins.
- November 1997: Great Wall begins installing trial CDMA network.

OFF

- March 1998: China postpones approval of Qualcomm's manufacturing plants, delaying regional CDMA phone systems in Xian, Beijing, Shanghai and Guangxi.
- February 1999: China imposes moratorium on deployment of CDMA, according to news reports.

ON

- April 1999: Qualcomm's stock jumps on reports that China's telecom ministry plans to buy \$500 million worth of CDMA equipment.

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OFF?

- May 8, 1999: U.S. accidentally bombs Chinese Embassy during Bosnian conflict, putting chill into U.S.-China relations.

ON?

- November 1999: U.S. agrees to support China's entry into the World Trade Organization.
- February 2000: Qualcomm drafts deal with China Unicom (government authorized carrier) for a nationwide CDMA network.

OFF?

- Within days, news reports state that the Chinese government has delayed the CDMA network indefinitely.

ON

- March 2000: Chinese Premier Zhu Rongji denies any delay in rolling out CDMA.
- June 2000: Qualcomm licenses CDMA technology to eight Chinese manufacturers.
- September 2000: Senate approves normalizing trade relations with China, an important step for entry into the WTO.
- December 2000: China's telecom ministry backs deployment of a nationwide CDMA network.
- March 2001: Unicom invites companies to bid on multibillion-dollar CDMA network.

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OFF?

- April 2001: U.S. spy plane collides with Chinese fighter jet and lands in China.
- May 1, 2001: Unicom postpones awarding CDMA contracts.

ON?

- May 10, 2001: Chinese President Jiang Zemin tells business leaders, including Qualcomm CEO Irwin Jacobs, that it would be useful to have CDMA in China.
- May 16, 2001: Unicom signs CDMA equipment contracts worth \$1.5 billion with Ericsson, Motorola and others.
- May 25, 2001: Spy plane incident resolved.
- July 2001: Qualcomm opens center in China to provide training for CDMA. November 2001: China accepted into the WTO. Unicom says it will deploy its CDMA network in January.
- December 2001: Bush formalizes permanent normal trade status with China.
- January 2002: Unicom launches national CDMA wireless network.

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BACKGROUND CONSIDERATIONS

1. There was significant in-fighting between the Ministry of Electronics Industries (MEI) and the Ministry of Posts and Telecommunications (MPT). MPT had a monopoly but in 1993, MEI was approved to form a second carrier known as China Unicom. MPT, which was using GSM, worked to slow entry of CDMA. In 1998 MEI and MFT were both abolished and a new Ministry of Information (MII) was formed.
2. CDMA was viewed as American technology and its fate often rose and fell with US-China relations. China used CDMA as a bargaining chip to push US support for China's admission to WTO. The US sometimes also pushed for CDMA in exchange for support

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3. In 1998, the Great Wall (formed by MPT and the People's Liberation Army) failed to get approval from MII for permanent operation. China Unicom was also ordered to stay with GSM officially to conserve funding for transition to the expected 3G network.
4. In March 1998, the US Secretary of Commerce William Daley lobbied hard for CDMA in China.
5. In 2000. MII said a decision on CDMA was on hold pending resolution of the WTO bid and trade agreements with the US going through Congress.

OTHER REPORTED POTENTIALLY IMPACTING FACTORS

The Chinese government was reportedly unhappy with the terms of the initial deal between Qualcomm and China Unicom. Qualcomm later reduced fees.

Chinese manufacturers needed more time and technology transfer to be ready to make CDMA equipment.

In 2000, Qualcomm brought along Brent Scowcroft to meetings. Scowcroft had been National Security Advisor to Presidents Ford and Bush and in that capacity was one of the few Western leaders to visit Beijing soon after the Tiananmen Square incident.

UPDATE –NOVEMBER, 2013 MORE OF THE SAME?

China has launched an investigation of Qualcomm under the country's Anti-Monopoly Law. Though the law has been used generally to keep prices and inflation down, likely contributing factors include the fact that China Mobile is preparing to introduce high speed 4G wireless and will need to negotiate license and component purchase from Qualcomm.

But not coincidentally, there have also been growing security related tensions between the US and China with a U.S. congressional investigation concluding that Huawei (a large Chinese company) posed security risks to the U.S. because their telecom equipment could be used for spying on Americans. The China action may be retaliation.

WHY IS PARTICIPATION IN STANDARDS DEVELOPMENT SO IMPORTANT?

- Push strategic agenda; influence standards (encourage favorable, block unfavorable)
- Build relationships
- Help assess strengths and vulnerabilities
- Use as test bed for new ideas
- Learn (from how discussed):
 - Current, potential competitors' thinking
 - Current emerging alliances
 - Technology evolution paths; research directions

STANDARDS DEVELOPMENT NEGOTIATION

VERY QUICK REVIEW OF NEGOTIATION BASICS

- Define your own interests and goals (continually refine)
- Assess interests and goals, absolute positions of other parties in the negotiation
- Seek agreement that maximizes your profit (this may mean first “growing the pie”, and could lead to pulling out of negotiation)
- Particularly if you will need to negotiate again with some of all of the same parties and given the need to implement agreement, work to help them to be comfortable with the agreement
- Multi-party negotiation (including standards) involve dynamic (shifting) alliances among parties

ADDED COMPLEXITY IN STANDARDS NEGOTIATION

Standards negotiators reflect multiple perspectives:

- corporate/organizational goals (doing what's right for company)
- national interests (doing what's best for country)
- industry, global community (doing what will work best and advance field)
- personal (pride) or pre-established relationships
- strategic – give in now for support in later negotiations

Derived from Carl F. Cargill, *Why Standardization Efforts Fail*, Journal of Electronic Publishing, 2011

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ADDED COMPLEXITY IN STANDARDS NEGOTIATION (CONTINUED)

- Understanding of own interest already a challenge. Standards can be a platform impacting across organization and both current and uncertain future competitive position; ideal rep needs both technical and strategic/management understanding
- First task in actual negotiations: agreeing on rules
- Parties are often very mismatched- differing in
 - types of organizations ranging from governments to industry to other stakeholders,
 - levels and standing of individual representatives,
 - varying agendas, knowledge bases, and experience in target domain and standards setting in general,
 - cultures and development stages

- Goals of participation extend beyond “winning”; consequences of pulling out can be significant and negotiations & standards setting will continue without you
- Likely will encounter parties again with different starting alliances and perhaps changed agendas
- Need to establish credibility to really negotiate (expand on this shortly)
- Process is often argumentative
- Negotiations often have an informal as well as formal component
- **Success of standards development determined by acceptance and implementation of standard**

EXAMPLE QUESTIONS FOR NEGOTIATION PLANNING

- Whom/what do I represent? How could my company's needs change? What is critical to me? What authority do I have?
- What do I know and not know? What can/should I learn from the negotiations?
- Who is at the table? Whom/what do they represent? How are they interrelated? How might their needs change?
- What is the position, authority and standing of the representatives? How might negotiations change if the reps change?

- What do they know and not know? Can I expand their knowledge productively?
- Who could block? Who might enable?
- How are current negotiations linked to other negotiations? Who might I need in the future and how?
- What are my underlying assumptions (and those of other parties)?
- What are my competitive strengths and weaknesses? How might these change?

NUZIP STANDARDS DEVELOPMENT EXERCISE (1)

This exercise is intended to help introduce through experience multiple dimensions and complex motivations often involved in standards negotiation (with subtleties that are difficult to convey otherwise.) Though some technical background is given, emphasis is more on strategic issues than technical merit. The technology/performance standard example is highly simplified – discussion after working through the exercise in a class setting might delve into deeper issues in emerging technologies/systems, as well as broader marketing, finance, political, organizational, design etc. considerations.

NUZIP STANDARDS DEVELOPMENT EXERCISE (2)
CHALLENGES UNDERLYING
STRONG INDUSTRY PRESSURE FOR NEW STANDARD

- Multiple and growing number of machines and devices on factory floor and beyond that need to be interconnected
- Continually evolving IT technologies and analytic potential, stakeholder expectations (including integration with broader office systems) and emerging demands of cross-enterprise smart grid pushing increased speed and accuracy of data throughput
- Increased speed and interconnections heightening security risks

NUZIP STANDARDS DEVELOPMENT EXERCISE (3)

TECHNICAL TRADE-OFFS ADDRESSED IN EXERCISE

- System-wide speed of throughput
- Determinism (reaction time – speed required data is received and confirmed, and extent to which this is consistent and predictable); mitigates throughput speed
- Complexity (difficulty in set up and maintenance – how much expertise and training is required); difficulty is transitioning from legacy systems

NUZIP STANDARDS DEVELOPMENT EXERCISE (4)

You have been assigned to represent one of 5 countries (A-E) which have varying concerns related to a technology (which has a de-facto/ market determined standard) and has different goals in negotiations to develop a formal new standard. Some of you have instead been designated as a “Chair” /Secretariat.

You have been given general background and a role-specific briefing on your position. PLEASE REVIEW.

TASKS

- Assess needs and concerns, define basic strategy – both ideal and fallback position
- Identify and assess positions and foundations of other participants, refine strategy
- Pursue strategy through both open session and, as appropriate and necessary, private interaction during breaks

NUZIP STANDARDS DEVELOPMENT EXERCISE (5)
KEY UNDERLYING TECHNOLOGY: NUZIP

Country A firms originated technology and are market leaders; Country A firm only one with demonstrated (and now patented) high speed approach. Country C is evolving alternative, incompatible, approach which may have advantages - but no time line for commercial launch.

There is strong industry pressure for high speed standard to guide and support investment planning.

**NUZIP STANDARDS DEVELOPMENT EXERCISE (5)
COUNTRY A PROPOSED DRAFT STANDARD**

1. The standard for NUZIP will be high speed: 10 mbs -1 gb throughput speed with less than 1 mbs reaction time.
2. The technology will be based on the Country A approach including its level of safety and security.
3. It will be backward compatible and support use at lower levels.

If a standard is not approved in the current session, it will be put off until at least next year

NEGOTIATION PROCESS AND INSTRUCTIONS

STAGES

1. 15 minutes preparation within groups

Use this time to review role assignments and consider strategy. While you cannot embellish or change the technology, you can and should be creative in anticipating other parties' positions (refining assessment as negotiations proceed), how you can address them and how they might respond. What is critical to you? What will you reveal - or not – and when about your interests and thinking? What do you need, how urgently? Who might be allies? Who might be enemies?

2. 20 minutes formal negotiation:

Each group will make brief opening statements and then offer further comments and counterpoints/questions with permission of Chair, The Chair can call for a vote at any time. Voting will follow ISO rules with a consensus (approval of standard) determined by agreement of 2/3 of voting participants (in this case 4 of 5 voting participants).

NEGOTIATION PROCESS AND INSTRUCTIONS

3. **15 minute break** (you may use this time for informal interactions with other groups)
4. **15 minutes formal negotiation**
5. **15 minute break** (you may use this time for informal interactions with other groups)
6. **10 minutes final formal negotiations** (f necessary)